

REMARKS**Specification**

The Office communication indicated that the title of the invention is not descriptive. Accordingly, a more descriptive title is provided.

In an earlier amendment, the cross reference to related applications was amended to remove the cross reference to two patent applications that have now issued into patents. By so doing, the incorporation by reference for these two applications was inadvertently removed. The amendment to the specification is intended to correct this error and to reinstate the incorporation by reference of these two applications.

Claim Rejections -- 35 USC §102

Claims 71, 72, 75, 76, 78-90 were rejected as being anticipated by DeFord et al. (US 5,304,214). Independent claims 71, 82, and 87 have been amended to claim a standalone implantable power module that can be used to power a variety of different medical electronic devices or a method of using a standalone implantable power module that can be used to power a variety of different medical electronic devices. In '214, the power supply 38 is included within the internal control unit 16, which includes RAM 94 that enables a patient to be able to undergo hyperthermia treatment while away from the external control unit 22. That is, the power supply 38 is located within the medical device itself, internal control unit 16. Clearly, '214 does not teach a standalone implantable power module that can be used to power a variety of different medical devices.

Claim Rejections -- 35 USC §103

Claims 73, 74, and 77 were rejected as being unpatentable over DeFord et al. (US 5,304,214). The Office communication stated:

Regarding claim 73, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the power source with at least one primary battery, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art.

However, it is submitted that Applicant's invention does not *omit* an element; it *adds* a primary battery. Furthermore, these claims depend from claim 71, which should patentable for the reasons that claim 71 is patentable.

Double Patenting

Claims 71-90 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 71-336 of copending Application No. 10/310,390. Applicant believes that the amended and newly added claims are patentable over claims 71-336 of copending Application No. 10/310,390. If it is determined that a terminal disclaimer is still necessary to overcome the rejection, the Examiner is respectfully requested to telephone the undersigned.

Conclusion

Favorable consideration of the claims is thought to be in order and is courteously solicited.

Respectfully submitted,



MARY ELIZABETH BUSH

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Office Action Summary

| | |
|---|--|
| Application No. 10/310,390 Examiner Edward H Tso | Applicant(s) TSUKAMOTO ET AL. Art Unit 2838 |
|---|--|

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19, 31-33, 36-65, 67 and 68 is/are rejected.
- 7) Claim(s) 20-30, 34, 35, 66, 69 and 70 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 November 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | <ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____ |
|---|---|

DETAILED ACTION

Information Disclosure Statement

The IDS filed 11/19/2003 and its duplicate filed 11/24/2003 have been considered placed of record. An initialed copy is attached herewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 10, 17, 31-33, 67 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by MICHELSON (US 6,120,502). The reference discloses, *inter alia*, an implantable power module 80 having a hermetically sealed casing made of metal such as titanium (column 8, line 64), a power supply 60, a power control management circuit 70. see column 9, lines 9-13. It further discloses a couple for remotely communicate with the power supply through induction and electrically connected to the circuit 70. See column 9, lines 46-54. And a connector 50 for connecting to an implantable medical device 10. See column 9, line 2. The power control providing various patterns of charge to ensure the promotion of the medical device. See column 9, lines 25-45.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 7-9, 11, 18, 19 and 36-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over MICHELSON (US 6,120,502) in view of ECHARRI et al. (US 6,278,258). Reference '502 fails to disclose the specific features of its power controller.

Reference '258 specifically teaches an implantable power management system located inside the implantable device having, *inter alia*, processor for supervising the charging and discharging operation of the power module being rechargeable battery or capacitors (column 1, line 49). See column 5, lines 5-40. It senses and responses to temperature changes, charging capacity, overcharge ect. to the power module. The communication may be done by rf means. It would have been obvious to one having ordinary skill in the art to have employed the features of

the power management controller of '258 to the controller of '502 in order to not only control and monitor the discharge of the power module but actually control the charging of the power module to provide a safer and more reliable implantable device.

Furthermore both references don't disclose the various communication means including light, coil ect. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have employed any appropriate communication means, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 3 and 46-65 rejected under 35 U.S.C. 103(a) as being unpatentable over MICHELSON (US 6,120,502) in view of GARGANO et al. (US 5,629,678). Reference '502 fails to disclose a homing device imbedded on the implantable device in order to track it. Reference '678 teaches an apparatus for tracking using an implantable receiver. It uses radio frequency to track and recover the device. It would have been obvious to one having ordinary skill in the art to have placed a homing device in the medical device for the purpose of relocating and facilitate the rapid recovery of the device.

Furthermore, both references do not disclose the many different homing devices including those that uses light, radioactive isotope ect. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the appropriate homing signal for the implantable device and/or affecting patient, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its

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suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected any appropriate range of light since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 4, 6 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over MICHELSON (US 6,120,502). Reference does not disclose the power module being a primary battery and or the battery/power controller is partially surrounded by ferrite coil for inductive coupling. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the power module to include nonrechargeable batteries and surround the battery and/or power controller with ferrite coil to induce inductive charging, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

Claims 20-30, 34, 35, 66, 69 and 70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The references made of record fails to disclose or suggest an energy drain circuit for rapid depletion of the energy in the power module (claims 20-25), a heat absorption material in thermal contact with the storage device (claims 26-

Art Unit: 2838

30), the medical device/implantable module is remotely located from the power module through an external hermetically sealed plug (claims 34, 35, 69 and 70) and an extra connector for an additional device (claim 66).

Conclusion

Any inquiry concerning this communication should be directed to the Examiner at the below-listed number.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is 703 308 0956, Monday-Friday, 830am to 5:00pm, EST.

By:



EDWARD TSO
Primary Examiner
703 308 2823



| | | | | | |
|--|---|----|---|------------------------|--------------------------|
| Substitute for form 1449A/PTO | | | | Complete If Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Application Number | 10/310,390 |
| | | | | Filing Date | December 5, 2002 |
| | | | | First Named Inventor | Hisashi Tsukamoto et al. |
| | | | | Art Unit | 2838 |
| | | | | Examiner Name | Edward H. Tso |
| Sheet | 1 | of | 1 | Attorney Docket number | Q147-US1 |

| | | | |
|--------------------|---|-----------------|-------|
| Examiner Signature |  | Date Considered | 01.04 |
|--------------------|---|-----------------|-------|

'EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form which next communication to applicant.

'Applicant's unique citation designation number (optional): ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

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|-----------------------------------|--|-------------------------|---|-------------|
| Notice of References Cited | | Application/Control No. | Applicant(s)/Patent Under Reexamination | |
| | | 10/310,390 | TSUKAMOTO ET AL. | |
| | | Examiner | Art Unit | Page 1 of 1 |
| | | Edward H Tso | 2838 | |

U.S. PATENT DOCUMENTS

| * | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | Classification |
|---|--|-----------------|------------------------|----------------|
| A | US-5,629,678 | 05-1997 | Gargano et al. | 340/573.4 |
| B | US-6,120,502 | 09-2000 | Michelson, Gary Karlin | 606/61 |
| C | US-6,278,258 | 08-2001 | Echarri et al. | 320/130 |
| D | US-6,426,628 | 07-2002 | Palm et al. | 324/427 |
| E | US- | | | |
| F | US- | | | |
| G | US- | | | |
| H | US- | | | |
| I | US- | | | |
| J | US- | | | |
| K | US- | | | |
| L | US- | | | |
| M | US- | | | |

FOREIGN PATENT DOCUMENTS

| * | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Country | Name | Classification |
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NON-PATENT DOCUMENTS

| | | | |
|---|---|--|--|
| * | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) | | |
| U | | | |
| V | | | |
| W | | | |
| X | | | |

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
MARY ELIZABETH BUSH
QUALLION LLC LEGAL DEPARTMENT
12744 SAN FRANANDO RD.
P.O. BOX 923127
SYLMAR, CA 91392-3127

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

01 JUN 2004

Applicant's or agent's file reference

Q147-PC1

IMPORTANT NOTIFICATION

| | | |
|-------------------------------|--|--------------------------------|
| International application No. | International filing date (day/month/year) | Priority date (day/month/year) |
| PCT/US03/24168 | 31 July 2003 (31.07.2003) | 09 August 2002 (09.08.2002) |

Applicant

QUALLION LLC

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US
Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Authorized officer

Michael Sherry

Telephone No. 571 272 2800

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

| | | |
|---|---|---|
| Applicant's or agent's file reference Q147-PC1 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US03/24168 | International filing date (<i>day/month/year</i>) 31 July 2003 (31.07.2003) | Priority date (<i>day/month/year</i>) 09 August 2002 (09.08.2002) |
| International Patent Classification (IPC) or national classification and IPC IPC(7): H01M 10/46 and US Cl.: 320/112 | | |
| Applicant QUALLION LLC | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 2 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

| | |
|---|---|
| Date of submission of the demand 09 March 2004 (09.03.2004) | Date of completion of this report 13 April 2004 (13.04.2004) |
| Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | Authorized officer  Michael Sherry Telephone No. 571 272 2800 |

I. Basis of the report**1. With regard to the elements of the international application:***

the international application as originally filed.

the description:

pages 1-12 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____.

the claims:

pages 13-20, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of _____.

the drawings:

pages 1-10, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____.

the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item:

These elements were available or furnished to this Authority in the following language _____ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in printed form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

the description, pages NONE

the claims, Nos. NONE

the drawings, sheets/fig NONE

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-70</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive Step (IS) | Claims <u>1-70</u> | YES |
| | Claims <u>NONE</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-70</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-70 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an implantable power module comprising, inter alia, a hermetically sealed biocompatible case; an electrochemical energy storage device housed within said case; a power management circuit housed within said case; a couple for remotely communicating with said power module; said couple electrically connected to said power management circuit; and at least one connector for functionally interconnecting said electrochemical energy storage device to an implantable medical device.

Claims 1-70 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

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